

**REMARKS**

Claims 54, and 57-91 are now pending in this application. Prior to this amendment, claims 54-91 were pending in the application. By this amendment, claims 54, 68, 77, 84, and 90 and 91 are herein amended, and claim 55 is deleted. For the reasons discussed in detail below, Applicants respectfully submit that the application is now in condition for allowance.

**I. Rejection of Claims 54-91 Under 35 U.S.C. 112, first paragraph**

The Examiner has maintained the rejection of claims 54-91 under 35 U.S.C. 112, first paragraph, on the basis that the claims contain subject matter which is not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which is most clearly connected, to make and/or use the invention. In particular, the Examiner contends that (1) the claim language "fragments or derivatives thereof" renders the claims non-enabling because the structure of the epitope is not set forth, and that without guidance as to what the structure of the immunogen looks like, one of skill in the art would be hard pressed to determine which antibody derivatives are capable of specifically binding an antigen of undisclosed structure; and that (2) the claim language "an epitope of an antigen" renders the claims non-enabling because the claims do not set forth the structure of this epitope, and that one of skill would be forced into excessive experimentation to determine which epitope of unknown structure is capable of retaining a structure after intestinal passage similar enough to bind an antibody that also binds the native structure prior to intestinal passage.

Applicants respectfully traverse the Examiner's rejections on the grounds already of record. However, in order to expedite prosecution of this case, Applicants herein amend claims 54, 57, 68, 77, and 84 to put the application in condition for immediate allowance. These amendments are made without prejudice or disclaimer. As amended, (1) the method of claimed invention is limited to that for detecting an infection of an acid-resistant microorganism belong to the genus *Helicobacter* in a human; (2) the language "monoclonal antibody or fragment or derivative thereof" has been replaced with "monoclonal antibody or "Fab-, F(ab)'<sub>2</sub>, Fv-, or scFv-fragments thereof"; and (3) the terms "epitope of a first antigen" and "epitope of a second antigen" has been limited to that of an antigen selected from a specific group of proteins. Support for the amendments can be found on at least pages 7 (e.g., last paragraph) and 11 (e.g., 3<sup>rd</sup> and 4<sup>th</sup> full paragraphs) of the specification.

Applicants respectfully submit that, as herein amended, the subject matter of the claimed invention is clearly described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Accordingly, the rejection of claims 54-91 under 35 U.S.C. 112, first paragraph should be reconsidered and withdrawn.

**II. Rejection of Claims 54-91 Under 35 U.S.C. 112, second paragraph**

The rejection of claim 54-91 under 35 U.S.C., second paragraph, is also maintained on the basis that the claims are vague and indefinite in the recitation of "derivative." In particular, the Examiner contends that, "Derivative as defined by Dorlands Medical Dictionary 27<sup>th</sup> Edition, 1998 is a substance derived from another substance 'either directly or by modification.' The degree of the substance can be modified and still remain under the scope of a derivative, simply cannot be determined by one of skill in the art."

As herein amended, the term "derivative" has been deleted from the claims, thereby rendering the Examiner's rejection of claims 54-91 under 35 U.S.C. 112, second paragraph moot.

**III. Conclusion**

Having responded to all rejections and objections set forth in the outstanding Office Action, it is submitted that claims 54, and 57-91 are now in condition for allowance. An early and favorable Notice of Allowance is respectfully solicited. In the event that the Examiner is of the opinion that a brief telephone or personal interview will facilitate allowance of one or more of the above claims, the Examiner is courteously requested to contact Applicants' undersigned representative.

Respectfully submitted,

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